

Remarks:

For convenience, Pages 2 and following of the official action are presented below with corresponding responses interspersed between paragraphs:

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DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group IV in Paper No. 6 is acknowledged.
Claim Rejections - 35 USC § 112

The rejection of claims 10 and 20-27 under 35 U.S.C. 112, second paragraph, are withdrawn in view of the amendments.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Morris et al (J. Gen. Microbiol. (1978) 106:387-389).

As an initial matter prior to the rejection, the claims must be construed. These claims are construed using the broadest reasonable interpretation where the intended use limitations are not given patentable weight since they do not limit the compositions in any structural sense.

Morris teaches a lysis composition which comprises 5 mM spermidine, to which is added the detergent SDS which is a lysing reagent (see page 387, paragraph 2).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: [Page 3]

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 10, 19-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morris et al (J. Gen. Microbiol. (1978) 106:387-389) in view of Stratagene Catalog (1988) p. 39

Morris teaches a lysis composition which comprises 5 mM spermidine, to which is added the nonionic detergent SDS which is a lysing reagent (see page 387, paragraph 2).

Morris further teaches the use of glass centrifuge tubes, which is an apparatus which permits application of the method in parallel as well as the use of centrifugation apparatus (see page 387, paragraph 2). In a kit, as taught by Stratagene below, multiple vials of the same solution are commonly used to minimize contamination. Morris teaches a first compaction precipitation solution which is the cold lysis buffer with spermidine (see page 387)

a stripping solution, which is the phenol solution (which is an alcohol) mixed with a Tris/HCl salt (see page 387) a Tris resuspension solution (see page 387) and a second compaction solution, which is the PEG solution (page 388).

Morris teaches filtering the nucleic acid through an agarose gel (see figure 1 on page 388) as well as the apparatus for its use which has multiple lanes (see figure 1 on page 388). [Page 4]
Morris does not teach placement of these reagents into a kit format.

Stratagene catalog teaches a motivation to combine reagents into kit format (page 39).

It would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to combine the method of Morris into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit. "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantities of 10 different reagents, each of which is needed in only microgram

amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control" (page 39, column 1). Further, it would have been obvious to multiplex the method of Morris in order to perform multiple assays at the same time since this would permit improved efficiency and reduced cost.

Response to Arguments

6. Applicant's arguments filed February 4, 2003 have been fully considered but they are not persuasive.

Applicant has one primary argument, that the prior art reference of Morris does use the mixture of components for the same purpose that applicant does. In this, Applicant is entirely correct, Morris uses the mixture of components in an entirely different way than Applicant. But MPEP 2111.02 notes "Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art." It is clear that a structural difference must exist between the claimed invention and the prior art to overcome the rejection and not simply a difference in the intended use. As MPEP 2111.02 also notes "a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone."

In the current case, there are no structural differences between the claimed products and those of Morris. Morris has a solution which comprises a lysing means and spermidine without any of the excluded elements, as discussed in the rejection. The fact that Morris is using them in an entirely different way does not distinguish from the claimed invention.

Perhaps the clearest legal support for this principle is found in *In re Schreiber*, 128 F.3d 1473 (CAFC 1997). In *Schreiber*, the Applicant had invented a conical dispensing cap for dispensing only a few kernels of popcorn when the cap was attached [Page 5] to a base. The rejection relied upon an oil can dispenser to dispense oil. While these are obviously entirely different uses, and the reference relied upon in the rejection was dispensing a liquid and not a solid as in the claim, the Federal Circuit affirmed the rejection finding that the intended use did not distinguish between the prior art and the claimed invention. Similarly here, Applicant's citation of web pages which show methods of lysis are not relevant. The sole question is whether the prior art discloses the product, not whether the prior art uses the product in the same way as applicant. Applicant's method claims in 09/609,996 were properly allowed based upon method limitations, but these same limitations are not applicable to product claims.

Applicant argues that Morris's method, ultimately, uses components which Applicant avoids. Given the scope of the claims, this argument is not relevant since it goes to the intended use of the method, and not to any structural difference. With regard to the claim amendment to "consisting essentially of," without any definition in the specification of what is "essential", this term is read as commensurate in scope to "comprising". Therefore, these rejections are maintained. Conclusion 7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

The phrase "consisting essentially of" has acquired special meaning in the law, and thus need not be defined in the specification. See e.g. *Atlas Powder v. du Pont* 750 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1984): "The phrase "consisting essentially of" excludes ingredients that materially affect the basic and novel characteristics of the claimed composition [kit]."

The Manual of Patent Examining Procedure § 2111.03 states: "If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964)". Here, the addition of the materials required by

Morris but not recited in the claims would render the kit suitable for the process of Morris but

unsuitable for the process taught by Applicants. The process of Applicants' has already been found unobvious and patentably distinct by the USPTO allowance of the parent case. A glance at Morris and at any of Applicants' Examples makes clear that adding Morris' materials would "materially change the characteristics of applicants'" claimed kits. Such an addition of materials would increase the cost and complexity of the kits as well as prolong the separation process to which they would be applicable. Morris' process is markedly different from Applicants' and the kits define the process.

The manufacturing of the kits of the present invention involves a *selection* of which items (reagents, etc.) are to be included in the kit. This selection is unobvious, even to one skilled in the art, until the present specification is read. If all the reagents required by Morris were included in the kit, many would be unnecessary and wasted. Conversely, if the presently claimed kits were used for the process of Morris, one could not complete the process of separation. Therefore one skilled in the art would not know how to select the items in the claimed kits. Reading both Morris and Strategene would not assist and Morris would instead "teach away" from the presently claimed kits by teaching that many more reagents are required for the separation.

Claim 10 recites a "...composition comprising a mixture of combined reagents, one of which comprises lysing means for releasing DNA from cells, and one of which comprises precipitating means having small, cationic molecules which bind in either the major or minor grooves of a double-stranded RNA or DNA molecule reducing the volume occupied by the nucleic acid which precipitates DNA comprising less than about 0.1 Units endotoxin per microgram plasmid DNA (EU/ μ g or IE/ μ g)." Neither Strategene nor Morris recites or suggests any such combined reagent composition.

Therefore, it is respectfully urged that the presently claimed kits and combined reagent compositions are unobvious under 35 U.S.C. 103.

Accordingly, Applicant is entitled to a patent under the mandate of 35 U.S.C. 101.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within [Page 6]TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-3086568. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308 0196.

Jeffrey Fredman Primary Examiner

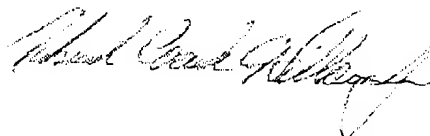
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The claims have been clarified and broadened merely by addition of wording from the original specification; no new matter has been added and no estoppel is involved. The changes were not required by the art cited because the original claims themselves distinguished from the references relied on.] No references were cited which were not relied on for rejections.

Any necessary (small entity) charges can be charged to USPTO Deposit Account 20-336 of Technology Licensing Co. LLC. Correspondence may be addressed to Customer No. 26830.

The Examiner is especially invited to telephone Applicants' Attorney if that would expedite prosecution and disposal of this Application.

Respectfully submitted,



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